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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
082,051	GYSIN et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P ri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ~~_____~~ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-29 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-29 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Claims pending are 1-29.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 23 and 27, drawn to a method of preparing monoclonal antibodies, classified in class 435, subclass 70.21 and in class 436, subclass 548, for example.

II. Claims 5-6, 20-21, 24-26 and 29, drawn to monoclonal antibodies and hybridomas secreting such, classified in class 435, subclass 326+ and in class 530, subclasses 387.3 and 388.1+, for example.

III. Claims 7, 12-14 and 28, drawn to antigens, classified in class 424, subclass 184.1+; class 530, subclass 300+; and class 536, subclass1.11+, for example.

IV. Claims 8-11, drawn to process of identifying an antigen binding a monoclonal antibody, classified in class 435, subclass 7.1+ and class 436, subclass 543.

V. Claims 15-19, drawn to processes of using a monoclonal antibody in immunizing/diagnosing/targeting, classified in class 424, subclasses 1.1+ and 130.1+; class 435, subclass 7.1+; and class 436, subclass 518+.

VI. Claim 22, drawn to a process of screening for an "active molecule" capable of reacting with an antigen, classified in class 436, subclass 501+.

The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product obtained is not structurally or qualitatively different from hybridomas/monoclonal

antibodies obtained by a "classical process" for obtaining such. As far as the examiner can determine, the method of Group I merely increases the frequency at which hybridomas can be obtained that may secrete monoclonal antibodies against a neo- or non-self antigen. The hybridoma cells, however, do not have any properties that differ from those obtained less frequently by a "classical process." The monoclonal antibodies secreted do not have any properties (e.g. better binding affinity constants) different from monoclonal antibodies secreted by hybridomas obtained by a "classical process." As such, the claimed monoclonal antibody product/composition is not different from the prior art.

Inventions I and V are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the generic monoclonal antibody product is not allowable, restriction is proper between said method of making and method of using. The product claim to a particular species of monoclonal antibody/hybridoma (see election of species requirement infra)will be examined along with the elected invention (MPEP § 806.05(i)). Since the monoclonal antibody product obtained by the process of Group I is not different from an antibody obtained by a "classical process," any process of using such a monoclonal antibody in a conventional use thereof, such as immunization, diagnosis or therapy, would not be distinct from any such process of using prior art, "conventional" monoclonal antibodies.

Inventions IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the

antigen product of Group III could be obtained by a different process. Steps (a)-(e) of the process of claim 9 of Group IV, like the process of Group I discussed supra, produce a monoclonal antibody that is not different from a monoclonal antibody obtained by the prior art, "classical process"; therefore, the cognate antigen thereof, identified by steps (f)-(g) of claim 9 of Group IV, would not be any different from the cognate antigen of a like binding monoclonal antibody obtained by the prior art, "classical process". A neo-antigen (e.g. sialyl Lewis-X of carcinomas) has the same structural features whether it binds to a monoclonal antibody obtained according to steps (a)-(e) of claim 9 or to a monoclonal antibody obtained by the prior art, "classical process".

Inventions IV and VI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the generic antigen product is not allowable, restriction is proper between said method of making and method of using. The product claim to a particular species of antigen (see election of species requirement infra) will be examined along with the elected invention (MPEP § 806.05(i)). Since any antigen identified by the process of Group IV would not be different from the cognate antigen of a like binding monoclonal antibody obtained by the prior art, "classical process", any use of such an antigen would be no different from the like use of suc in the prior art. For example, a process of identifying what might be an "active molecule" capable of reacting with any neo-antigen (the examiner takes this to mean identifying an actively binding molecule, such as an enzyme, receptor, selectin, or another monoclonal antibody of the same CD group) is the same process, irrespective of whether the neo-antigen may have been identified by the steps of claim 9 of Group IV or have been identified as the cognate antigen of a like binding monoclonal antibody obtained by the prior art, "classical process".

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions II (monoclonal antibodies) and III (cognate antigens) are different compositions with different structural features and have different properties and uses.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group IV (using a monoclonal antibody to identify the cognate antigen thereof) and of Group V (using the monoclonal antibody in a process of immunizing/diagnosing/ targeting) are different processes that have different steps and achieve different ends.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In the event Group(s) II is elected, the following election of species requirement is stated:

This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant must elect a distinct species of monoclonal antibody, along with the corresponding hybridoma secreting such.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 5-6, 26 and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event Group(s) III is elected, the following election of species requirement is stated:

This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant must elect a distinct species of antigen (e.g. a particular protein, glycoprotein, glycolipid, or epitope thereof).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7, 13-14 and 28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event Group(s) IV is elected, the following election of species requirement is stated:

This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant is required to elect the process of Group IV limited to the identification of the cognate antigen that complexes with a particular species of monoclonal antibody.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 8-11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event Group(s) V is elected, the following election of species requirement is stated:

This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant must elect a process using a particular species of monoclonal antibody.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 15-19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event Group(s) VI is elected, the following election of species requirement is stated:

This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant is required to elect a process of screening for an "active molecule" that is capable of reacting specifically with a particular species of antigen.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A Saunders

DAVID SAUNDERS
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